CLAIM AMENDMENTS:

1. (Currently Amended) A method of using polymer microparticles to protect pharmaceutical effectiveness of a pharmaceutically active agent comprising:

combining ~~providing a pharmaceutically acceptable suspension comprising~~ (a) a pharmaceutically active agent ~~and~~ with (b) previously formed polymer microparticles, ~~wherein said pharmaceutically active agent and polymer microparticles are commingled within said~~ to form a pharmaceutically acceptable suspension; and

contacting said pharmaceutically acceptable suspension with an incompatible component that is incompatible with said pharmaceutically active agent, wherein said incompatible component comprises a metal or a polymer and wherein said incompatible component is a component of an endoluminal drug delivery catheter. ~~medical device, and wherein said polymer microparticles result in a pharmaceutical effectiveness of the pharmaceutically active agent that is greater than a pharmaceutical effectiveness of the pharmaceutically active agent when contacted with the incompatible component in the absence of the polymer microparticles.~~

2. (Previously Presented) The method of claim 1, wherein said incompatible component comprises a metal.

3. (Original) The method of claim 2, wherein said metal is selected from stainless steel and nickel-titanium superalloy.

4. (Withdrawn) The method of claim 1, wherein said incompatible component comprises a polymer.

5. (Withdrawn) The method of claim 4, wherein said polymer is selected from polyether ether ketone, polyimide, epoxy, nylon, acrylonitrile/butadiene/styrene polymers and polycarbonate.

6. (Canceled)

7. (Canceled)

8. (Previously Presented) The method of claim 1, wherein said polymer microparticles are latex beads.

9. (Withdrawn) The method of claim 1, wherein said polymer microparticles are polystyrene microparticles.

10. (Previously Presented) The method of claim 1, wherein said polymer microparticles range from 0.01 to 100 microns in largest dimension.

11. (Previously Presented) The method of claim 1, wherein the polymer microparticles range from 0.1 to 10 microns in largest dimension.

12. (Previously Presented) The method of claim 1, wherein the polymer microparticles are provided in an amount of 0.1 to 1 wt% in said suspension.

13. (Original) The method of claim 1, wherein the pharmaceutically active agent comprises a polynucleotide.

14. (Original) The method of claim 13, wherein the pharmaceutically active agent is a cell, a plasmid or a viral vector.

15. (Original) The method of claim 14, wherein the pharmaceutically active agent is a viral vector selected from an adenoviral vector and an adeno-associated viral vector.

16. (Canceled)

17. (Previously Presented) The method of claim 1, wherein said microparticles are polystyrene microparticles and wherein said pharmaceutically active agent is selected from a cell, a plasmid and a viral vector.

18 to 36. (Canceled)

37. (Previously Presented) The method of claim 1, wherein the polymer microparticles are provided in an amount of 0.01 to 10 wt% in said suspension.

38. (Canceled)

39. (Canceled)

40. (Currently Amended) The method of claim 39, wherein said endoluminal drug delivery catheter is a needle injection catheter.

41. (Previously Presented) The method of claim 40, wherein said needle injection catheter is adapted for endocardial, epicardial, or pericardial administration.

42. (Currently Amended) The method of claim 1, wherein said endoluminal drug delivery catheter is adapted ~~drug delivery medical device is a medical device~~ for parenteral injection.

REMARKS

Responsive to the Advisory Action mailed July 2, 2003 in the above matter, please consider the following remarks.

Claims 1-5, 8-15, 17, 37 and 40-42 are presently pending herein.

Claims 1, 40 and 42 are amended. Support for an endoluminal drug delivery catheter can be found, for example, in paragraph [0052] of the present specification. Support for combining a pharmaceutically active agent with previously formed polymer microparticles can be found, for example, in paragraph [0060] of the present specification.

The Office Action indicates that claims 4, 5 and 9 are withdrawn from consideration as directed to non-elected species. Claim 9, however, claims polystyrene microparticles (as opposed to a polymer incompatible component) and thus is not directed to a non-elected species as asserted in the present Office Action. Claims 4 and 5 have not been deleted at this time because, as indicated in the Office Action mailed July 16, 2002, the restriction requirement between the linked inventions is subject to the non-allowance of the linking claim (e.g., claim 1).

Rejection of Claims 1, 2, 7, 9-15, 17, 37-42 under 35 U.S.C. 102(e)--Mathiowitz

Claims 1, 2, 7, 9-15, 17 and 37-42 are presently rejected under 35 U.S.C. 102(e) as being anticipated by Mathiowitz et al., U.S. Pat. No. 6,248,720 B1 ("Mathiowitz"). Applicants respectfully traverse this rejection and its supporting remarks.

For example, claim 1 makes clear that the pharmaceutically acceptable suspension is formed by combining (a) a pharmaceutically active agent with (b) previously formed polymer microparticles. In Mathiowitz, microparticles are formed in the presence of the nucleic acids so as to encapsulate the nucleic acid within the microparticles. See, e.g., col. 1, lines 49-53 and lines 57-59, col. 4, lines 55-58, col. 5, line 63 to col. 6, line 9, Examples 1-4, etc. Thus , Mathiowitz neither teaches nor suggests combining (a) a pharmaceutically active agent with (b) previously formed polymer microparticles as presently claimed.

Furthermore, even assuming for the sake of argument that Mathiowitz did so, Mathiowitz nevertheless does not teach or suggest contacting such a composition with an incompatible metal or polymer component of an endoluminal drug delivery catheter, as presently claimed in claim 1.

In the present invention, microparticles are employed to substantially protect the pharmaceutical effectiveness of pharmaceutically active agents upon contacting incompatible metallic or polymeric materials. As a result of the presence of the microparticles, the pharmaceutically active agent is substantially protected upon contact with the incompatible materials. See paragraph [0026] of the present specification.

Note that the teachings at col. 13, lines 21-45 of Mathiowitz, referred to in the final Office Action of April 11, 2003, have nothing to do with an incompatible metal or polymer medical device component, much less a component of an endoluminal drug delivery catheter, as presently claimed. Rather, these lines refer to metal *compounds*, which are added to enhance bioadhesive properties.

For at least the above reasons, it is respectfully submitted that claim 1 is not anticipated by Mathiowitz.

Claims 2, 9-15, 17, 37 and 40-42, which depend from claim 1, are patentable over Mathiowitz for at least the same reasons. Claims 7, 38 and 39 are cancelled.

Accordingly, reconsideration and withdrawal of the rejection of claims 1, 2, 7, 9-15, 17 and 37-42 as being anticipated by Mathiowitz are respectfully requested.

Rejection of Claims 1-3, 7-8, 10-15, 17 and 37-42 under 35 U.S.C. 103(a)

Claims 1-3, 7-8, 10-15, 17 and 37-42 are presently rejected under 35 U.S.C. 103(a) as being obvious over Mathiowitz taken with WO 01/30403 ("Barry"). Applicants respectfully traverse this rejection and its supporting remarks.

The presently pending claims are patentable over Mathiowitz for the reasons set forth above, and Barry does not make up for the above noted deficiencies in Mathiowitz, because the publication date of Barry is May 3, 2001 and thus is subsequent to the filing date of the present invention.

For at least these reasons, it is respectfully submitted that claims 1-3, 8, 10-15, 17, 37 and 40-42 are patentable under 35 U.S.C. 103(a) over Mathiowitz in view of Barry. Claims 7, 38 and 39 are cancelled.

Reconsideration and withdrawal of the rejection of claims 1-3, 7-8, 10-15, 17 and 37-42 under 35 U.S.C. 103(a) are therefore respectfully requested.

CONCLUSION

Applicants submit that this application is in condition for allowance, early notification of which is earnestly solicited. The Examiner is encouraged to contact the undersigned at (703) 433-0510 to discuss any outstanding issues in this case.

FEES

The Office is authorized to charge any fees required in connection with this application to deposit account number 50-1047.

Respectfully submitted,

David B. Bonham
Registration No. 34,297

Attorney for Applicant
Mayer Fortkort & Williams, PC
251 North Avenue West, 2nd Floor
Westfield, NJ 07090
Tel.: 703-433-0510
Fax: 703-433-2362

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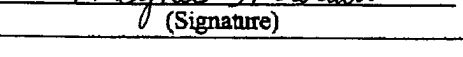

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